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(54) **Apparatus for use in spinal surgery**

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- **JOSE M OTERO VICH: 'Anterior cervical interbody fusion with threaded cylindrical bone' JOURNAL OF NEUROSURGERY vol. 63, November 1985, pages 750 - 753**

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Description

[0001] The present invention relates to an apparatus for use in human spinal surgery for fusing vertebrae.

[0002] The present invention includes an artificial fusion implant to be placed into the intervertebral space left after the removal of a damaged spinal disc.

[0003] The purpose of the present invention is to provide an apparatus for inserting an implant to be placed within the intervertebral disc space to provide for the permanent elimination of all motion at that location. To do so, the implant is space occupying within the disc space, rigid, self-stabilizing to resist dislodgement, stabilizing to the adjacent spinal vertebrae to eliminate local motion, and able to intrinsically participate in a vertebral to vertebrae bony fusion so as to assure the permanency of the result.

[0004] At present, following the removal of a damaged disc, either bone or nothing is placed into the space left. Placing nothing in the space allows the space to collapse which may result in damage to the nerves; or the space may fill with scar tissue and eventually lead to a reherniation. The use of bone is less than optimal in that the bone obtained from the patient requires additional surgery and is of limited availability in its most useful form, and if obtained elsewhere, lacks living bone cells, carries a significant risk of infection, and is also limited in supply as it is usually obtained from accident victims. Furthermore, regardless of the source of the bone, it is only marginal structurally and lacks a means to either stabilize itself against dislodgement, or to stabilize the adjacent vertebrae.

[0005] A review of related prior art will demonstrate the kind of the implant which may be used in the apparatus of the present invention.

[0006] There have been an extensive number of attempts to develop an acceptable disc prothesis (an artificial disc). Such devices by design would be used to replace a damaged disc and seek to restore the height of the interspace and to restore the normal motion of that spinal joint. No such device has been found that is medically acceptable. This group of prosthetic or artificial disc replacements, seeking to preserve spinal motion would include:

Patent No. 3,867,726 STUBSTAD - describing a flexible disc implant.

Patent No, 4,349,921 KUNT2 - describing a flexible disc replacement with file like surface projections to discourage device dislocation.

Patent No. 4,309,777 PATIL - describing a motion preserving implant with spiked outer surfaces to resist dislocation and containing a series of springs to urge the vertebrae away from each other.

Patent No. 3,875,595 FRONING - describing a motion preserving bladder like disc replacement with two opposed stud-like projections to resist dislocation.

Patent No. 2,372,622 FRENCH (FASSIO) - describing a motion preserving implant comprising complimentary opposed convex and concave surfaces.

[0007] In summary then, these devices are placed within the intervertebral space following the removal of a damaged disc. In that they seek to preserve spinal motion, they do not seek to permanently eliminate all motion at that spinal segment.

[0008] A second related area of prior art includes those devices utilized to replace essentially wholly removed vertebrae. Such removal is generally necessitated by extensive vertebral fractures, or tumors, and is not associated with the treatment of disc disease. While the implant used in the present invention is to be placed within the disc space, these other vertebral devices cannot be placed within the disc space as at least one vertebrae has already been removed such that there no longer remains a "disc space." Furthermore, these devices are limited in that they seek to perform as temporary structural members mechanically replacing the removed vertebrae (not a removed disc), and do not intrinsically participate in supplying osteogenic material to achieve cross vertebrae bony fusion. Therefore, use of this group of devices must by accompanied by a further surgery consisting of a bone fusion procefure utilizing conventional technique. This group consisting of vertebral struts rather than disc replacements would include the following:

Patent No. 4,553,273 WU - describing a turnbuckle like vertebral strut.

Patent No. 4,401,112 REZAIAN - describing a turnbuckle like vertebral strut with the addition of a long stabilizing staple that spans the missing vertebral body.

Patent No. 4,554,914 KAPP - describing a large distractible spike that elongates with a screw mechanism to span the gap left by the removal of a entire vertebrae and to serve as an anchor for acrylic cement which is then used to replace the missing bone (vertebrae).

Patent No. 4,636,217 OGILVIE - describing a vertebral strut mechanism that can be implanted after at least one vertebrae has been removed and which device consists of a mechanism for causing the engagement of screws into the vertebrae above and the vertebrae below the one removed.

[0009] In summary then, this group of devices are vertebral replacements struts, do not intrinsically participate in the bony fusion, can only be inserted in the limited circumstances where an entire vertebrae has been removed from the anterior approach, and are not designed for, or intended to be used for the treatment of disc disease.

[0010] A third area of prior art related to the present invention includes all devices designed to be applied to

one of the surfaces of the spine. Such devices include all types of plates, struts, and rods which are attached by hooks, wires and screws. These devices are not inserted within the disc space, and furthermore do not intrinsically participate in supplying osteogenic material for the fusion.

[0011] Therefore, with these devices where permanent spinal immobilization is desired an additional surgery consisting of a spinal fusion performed by conventional means or the use of supplemental methylmethacrylate cement is required. Such devices applied to the spine, but not within the disc space, would include the following:

Patent No. 4,604,995 - STEPHENS - describing a "U" shaped metal rod attached to the posterior elements of the spine with wires to stabilize the spine over a large number of segments.

Patent No. 2,677,369 - KNOWLES - describing a metal column device to be placed posteriorly along the lumbar spine to be held in position by its shape alone and to block pressure across the posterior portions of the spinal column by locking the spine in full flexion thereby shifting the maximum weight back onto the patient's own disc.

[0012] Other devices are simply variations on the use of rods (e.g. Harrington Luque, Cotrel-Dubosset, Zielke), wires or cables (Dwyer), plates and screws (Steffee), or struts (Dunn, Knowles).

[0013] In summary, none of these devices are designed or can be used within the disc space, do not replace a damaged disc, and do not intrinsically participate in the generation of a bony fusion.

[0014] Another area of related prior art to be considered is that of devices designed to placed within the vertebral interspace following the removal of a damaged disc, and seeking to eliminate further motion at that location.

[0015] Such a device is contained in Patent No. 4,501,269 BAGBY - describing an implantable device and limited instrumentation. The method employed is as follows: a hole is bored transversely across the joint and a hollow metal basket of larger diameter than the hole is then pounded into the hole and then filled with the bone debris generated by the drilling.

[0016] While the present invention may appear to bear some superficial resemblance to the BAGBY invention, it is minimal, while the differences are many fold and highly significant. These differences include the following:

1. Safety - The present invention provides for a system of completely guarded instrumentation so that all contiguous vital structures (e.g. large blood vessels, neural structures) are absolutely protected. Said instrumentation also makes overpenetration by the drill impossible. Such overpenetration in the cervical spine, for example, would result in the total paralysis or death of the patient. In the thoracic spine, the result would be completer paraplegia. In the lumbar spine, the result would be paraplegia or a life-threatening perforation of the aorta, vena cava, or iliac vessels. The implant used in the present invention is atraumatically screwed into place while the BAGBY device, in contradistinction, is pounded into position. BAGBY describes that the implant is significantly larger in size than the hole drilled and must be pounded in. This is extremely dangerous and the pounding occurs directly over the spinal cord which is precariously vulnerable to percussive injury. Furthermore, while it is possible, for example in the lumbar spine, to insert the implant used in the present invention away from the spinal cord and nerves, the BAGBY device must always be pounded directly towards the spinal cord.

Furthermore, since the BAGBY device is pounded into a smooth hole under great resistance, and lacking any specific design features to secure it, the device is highly susceptible to forceful ejection which would result in great danger to the patient and a clinical failure. The implant used in the present invention, in contradistinction, is securely screwed into place, and possesses highly specialized locking threads to make accidental dislodgement impossible. Because of the proximity of the spinal cord, spinal nerves, and blood vessels, any implant dislodgement as might occur with the BAGBY device might have catastrophic consequences.

2. Broad applicability - The BAGBY device can only be inserted from the front of the vertebral column, however, the present invention can be utilized in the cervical, thoracic, and lumbar spine, and can be inserted from behind (posteriorly) in the lumbar spine. This is of great importance in that the purpose of these devices is in the treatment of disc disease and probably greater than 99 percent of all lumbar operations for the treatment of disc disease are performed from behind where the present invention can easily be utilized, but the BAGBY device, as per his description, cannot.

3. Disc removal - The BAGBY invention requires the complete removal of the disc prior to the drilling step, whereas the present invention eliminates the laborious separate process of disc removal and efficiently removes the disc and prepares the vetebral end plates in a single step.

4. Time required - The present invention saves time over the BAGBY invention in that time is not wasted laboring to remove the disc prior to initiating the fusion. Also, since with the present invention the procedure is performed through a system of guarded instrumentation, time is not wasted constantly placing and replacing various soft tissue retractors throughout the procedure.

5. IMPLANT STABILITY _ Dislodgement of the im-

plant would be a major source of device failure (an unsuccessful clinical result), and might result in patient paralysis or even death. As discussed, the BAGBY device lacks any specific means of achieving stability and since it is pounded in against resistance to achieve vertebral distraction, it is susceptible to forceful dislodgement by the tendency of the two distracted vertebrae, to return to their original positions squeezing out the device. The present invention however is screwed into place. As there is no unscrewing force present between the vertebrae and compression alone cannot dislodge the implant, the implant is inherently stable by its design. Furthermore, the threads of the implant used in the present invention may be highly specialized in that they are periodically interupted such that the tail ends of each of the tabs so formed are blunted and twisted so as to resist accidental unscrewing. The removal of an implant with such "locking threads" requires the use of a special extractor included within the instrumentation. The stability of the implant is still further enhanced, again in contradistinction to the BAGBY device, by the presence of a "bone ingrowth" surface texturing, which both increases the friction of the fit and allows for the direct growth of the vertebral bone into the casing of the implant itself.

6. Spinal stability - The implant used in the present invention is not only self-stabilizing, it also provides stability to the adjacent vertebrae in at least three ways that the BAGBY device cannot. First, the BAGBY device is placed transversely across the joint in the center, leaving both vertebrae free to rock back and forth over this round barrel shaped axis, much like a board over a barrel, being used for a seesaw.

Secondly, as the BAGBY device lacks any specific design features to resist sliding, it may actually behave as a third body allowing the translation of the vertebrae relative to the device and to each other.

Thirdly, any device can only provide stability if it remains properly seated. The implant used in the present invention is inherently stable, and therefore assures that it will stabilize the adjacent vertebrae; rather than, as with the BAGBY device, where the instability of the spine to be treated may instead cause a dislocation of the implant, with further loss of spinal stability.

7. The collapse of the interspace - While both the implant of the present invention and the BAGBY device can be fabricated to withstand the compression forces within the interspace, the interspace may nevertheless collapse under the superincumbent body weight as the implant settles into the vertebral bone. This is related to the load per unit area. Again the implant in the present invention is superior to the BAGBY device in at least four ways. First, the implant in the present invention offers considerably greater surface area to distribute the load. Secondly, while the BAGBY device is placed centrally, the implant in the present device is placed bilateralllly where the bone tends to be more cortical and much stronger out towards the rim. Thirdly, the implant in the present invention supports the load achieving an "I" beam effect, whereas the BAGBY impland does not. Fourthly, it is not pressure alone that causes the collapse of the bone adjacent to the implant, but also bony erosion that is caused by the motion under pressure of the implant against the bone. As discussed in item #6 above, the implant in the present invention alone is highly resistant to such motion, again diminishing the likelihood of erosion and interspace collapse.

8. Bone ingrowth surface texturing - The implant in the present invention may have a surface treatment of known and conventional technology to induce the growth of bone from the vertebrae directly into the casing material of the implant itself. The BAGBY device has no similar feature.

[0017] The last area of prior art possibly related to the present invention and therefore, to be considered related to "BONY INGROWTH", and patents either describe methods of producing materials and or materials or devices to achieve the same. Such patents would include:

[0018] Patents No. 4,636,526 (DORMAN), No. 4,634,720 (DORMAN), No. 4,542,539 (ROWE), No 4,405,319 (CONSENTINO), No. 4,439,152 (SMALL), No. 4,168,326 (BROEMER), No. 4,535,485 (ASHMAN), No. 3,987,499 (SCHARBACH), No. 3,605,123 (HAHN), No. 4,655,777 (DUNN), No. 4,645,503 (LIN), No. 4,547,390 (ASHMAN), No. 4,608,052 (VAN KAMPEN), No. 4,698,375 (DORMAN), No. 4,661,536 (DORMAN), No. 3,952,334 (BOKROS), No 3,905,047 (LONG), No. 4,693,721 (DUCHEYENE), No. 4,070,514 (ENTHERLY).

[0019] However, while the present invention would utilize bone ingrowth technology, it would do so with conventional technology.

[0020] In EP 0077159, an apparatus is disclosed for use in performing the anterior fusion of cervical vertebrae by inserting a bone graft dowel between a pair of vertebrae. The apparatus includes a combined tubular vertebrae spreader and drill guide having a forward spreader end formed by two substantially semi-circular collar portions each having axially projecting pins for engagement into the vertebrae to be spread apart for insertion of the bone graft therebetween. The collar portions can firmly be held in their contracted positions by an outer collar when pushed along the spreader tube, thereby enabling the spreader tube to be used as a drill guide when drilling a hole across the spinal disk through the tube by use of a drill. when the outer collar has been moved to the rear end of the tube, the collar portions are freed to enable them to move apart. When the collar por-

tions are moved apart to their expanded positions, the bone graft dowel is inserted through the tube by means of an insertion tool. The outer diameters of the bone graft dowel and of the drill are substantially the same as the inside diameter of the tube. The combined vertebrae spreader and drill guide may be provided in different bore sizes depending on the diameter of dowel and drill used. The change in bore size may be accomodated by using removable inner sleeves of different bore diameter to be inserted into the tube.

[0021] Further, for insertion of bone grafts into the disc space, a device with an interchangeable head is known (J Neurosurg 63:750-753, 1985) that fits grafts of a variety of diameters. It is reported that the insertion of the threaded graft was carried out in a smoth manner without the use of intervertebral separators or other methods of traction. However, the reported instrumentation for performing the insertion of those threaded grafts is different from the instrumentation described in present claim 1.

[0022] In summary then, the apparatus of the present invention provides for a one stage discectomy, fusion, and interbody internal spinal fixation; that being performed more quickly, with greater safety, and more affectively, for all of the aforementioned reasons that is possible with any other known art.

[0023] The apparatus of the invention is described in claim 1. Embodiments are described in the subclaims.

[0024] An apparatus for preparing the vertebrae for insertion of the implant is disclosed, such apparatus and instrumentation allowing for the rapid and safe removal of the disc, preparation of the vertebrae, performance of the fusion, and internal stabilization of the spinal segment.

[0025] The purpose of the artificial implants is to participate in, and directly cause bone fusion across an intervertebral space following the excision of a damaged disc. Such implants are structurally load bearing devices, stronger than bone, capable of withstanding the substantial forces generated within the spinal interspace. Such device have a plurality of macro sized cells and openings, which can be loaded with fusion promoting materials, such as autogenous bone, for the purpose of materially influencing the adjacent vertebrae to perform a bony bond to the implants and to each other. The implant casing may be surface textured or otherwise treated by any of a number of known technologies to achieve a "bone ingrowth surface" to further enhance the stability of the implant and to expedite the fusion.

[0026] Further, said devices are so configured and designed so as to promote their own stability within the vertebral interspace and to resist being dislodged, and furthermore, to stabilize the adjacent spinal segments.

[0027] The instrumentation concept of performing various aspects of this surgery are not entirely new. Drills are frequently placed through hollow, tubular guards to protect the adjacent soft tissues. A set of instruments developed by Ralph Cloward utilizes such a tubular drill guard on a larger scale, for the purpose of drilling into the cervical spine. However, this inventor is unaware of any set of instruments, system, or procedure designed to allow the entire surgical procedure beyond the initial exposure, to be performed blindly and with complete safetly through a fixed sheath apparatus. Specific design features which combine to make this uniquely possible are as follows:

1. The availability of the specific implant.
2. The end of all the penetrating instrumentation is blunt faced.
3. All of the instruments have been stopped out at apredetermined depth to avoid overpenetration.
4. The design of the external sheath conforms to the spacial limitiations of the specific surgical site.
5. The design and use of a second or inner sheath allows for the difference in size between the inside diameter of the outer sheath, and the outside diameter of the drill itself. This difference being necessary to accommodate the sum of the distraction to be produced, and the depth of the circumferential threading present of the implant.
6. A specially designed drill bit with a central shaft recess allows for the safe collection of the drilling products, which can then be removed without disturbing the outer sheath by removing the drill bit and inner sheath as a single unit.
7. A specially designed trephine for removing a core of bone slightly smaller in diameter than the internal diameter of the implant cavity itself, however of a greater length.
8. A specially designed press for forcefully compressing and injecting the long core of autogenous bone into the implant, such that it extrudes through the implant itself.
9. A specially designed driver extractor, which attaches to the implant and allows the implant to be either inserted or removed without itself dissociating from the implant, except by the deliberate disengagement of the operator.

[0028] It is an object of the present invention to provide an improved apparatus for performing a discectomy, a fusion, and an internal stabilization of the spine, and specifically, all three of the above simultaneously and as a single procedure.

[0029] It is another object of the present invention to provide an improved apparatus for performing a discectomy, a fusion, and an internal stabilization of the spine in a quicker and safer way than is possible by previous apparatus.

[0030] It is another object of the present invention to provide an improved apparatus for performing a discectomy, a fusion, and in internal stabilization of the spine, to provide for improved surgical spinal implants.

[0031] It is another object of the present invention to provide an improved apparatus for performing a discec-

tomy, a fusion, and an internal stabilization of the spine, which provides for an improved system of surgical instrumentation to: facilitate the performance of the combined discectomy, fusion and internal spinal stabilization.

[0032] These and other objects of the present invention will be apparent from review of the following specifications and the accompanying drawings.

[0033] Figure 1 is a partial view of the vertebrae structure with the driver and outer sheath assembly of the present invention.

[0034] Figure 1A is a perspective view of the driver member for the outer sheath.

[0035] Figure 2 is a perspective view of the outer sheath being inserted into the vertebrae structure.

[0036] Figure 3 is a perspective view of the outer sheath and inner sheath assembly, with the drill bit of the present invention.

[0037] Figure 3A is a side sectional view of the collar and drill bit of Figure 3.

[0038] Figure 4 is a perspective view of a cylindrical implant and vertebrae structure.

[0039] Figure 4A is a perspective view of one preferred embodiment of the implant.

[0040] Figure 4B is a cross sectional view of the implant of Figure 4A.

[0041] Figure 4C is the driving and insertion equipment for the implant of Figure 4A.

[0042] Figure 4d is a side sectional view of the driver and implant between vertebrae.

[0043] Figure 5 is a sectional view of the vertebrae structure, taken along lines 5-5 of Figure 4.

[0044] Referring to Figure 1 a vertebrae structure comprising two vertebrae V and a disc D between the two vertebrae, is shown. A hollow tubular drill sleeve 10 has teeth 12 at its lower end. The sleeve 10 has an enlarged diameter upper portion 14.

[0045] A driver 16, shown in Figure 1A, consists of a solid tubular member 18 and an increased diameter head 20. The external diameter of the solid tubular member 18 is slightly smaller than the inside diameter of the hollow tubular drill sleeve 10 and has a length that is substantially shorter than the overall length of the hollow tubular drill sleeve 10.

[0046] The drill sleeve 10 is made of metal in order to be driven into the vertebrae V and be held in place by the teeth 12 of the drill sleeve 10.

[0047] Referring to Figure 2 the drill sleeve 10 with the driver 16 installed is shown being driven into two vertebrae V on either side of a disc D by hammer H.

[0048] Referring to Figure 3 and 3a the drill assembly is shown. In Figure 3 the drill sleeve 10 is illustrated in the two vertebrae V, straddelling the disc D.

[0049] A retaining sleeve 15 has an outside diameter slightly smaller than the inside diameter of the drill sleeve 10, and a length substantially the same length as the drill sleeve 10. The retaining sleeve 15 has a collar 17 at its upper end for engaging the top of the drill sleeve 10.

[0050] The drill 22 comprises an upper portion 24, a central recessed portion 26 and a lower cutting drill portion 28. The upper 24 and lower portion 28 of the drill 22 have the same outside diameter. The drill 22 has a collar (not shown) attached to the upper portion 24 of the drill 22.

[0051] The outside diameter of the drill 22 is slightly smaller than the inside diameter of the retaining sleeve 15. The length of the drill, from its collar to the end of the drill bit, is such that a predetermined portion of the drill bit 22 extends beyond the end 29 of the sleeve when fully inserted.

[0052] Referring to Figure 4, a cylindrical embodiment of the implant 50 is shown, one implant positioned in the opening in the vertebrae and disc formed by the drill 22, and a second implant shown prior to implantation.

[0053] The cylindrical implant 50 comprises a hollow tubular member which in the preferred imbodiment is made of an ASTM surgically implantable material, and preferably Titanium. The cylindrical implant 50 is closed at one end 52 and open at the other end 54. The outer cylindrical implant 50 has a series of macro-sized openings 56 through the side walls of the cylindrical member 50. A series of external threads 53 are formed on the circumference of the cylindrical implant 50. The threads 53 are locking threads having a series of interjections, the ends of which are blunted and twisted so as to resist unscrewing.

[0054] The open end 54 of the cylindrical implant 50 has an internal thread 51 for receiving a complementary cap 52 which has an external thread 58 for engaging the internal thread 51 of the cylindrical member 50. The cap 52 has a hexagonal opening 59 for use with an allen wrench for tightening the cap. A driver engaging element 70 is located on the rear surface 60 of the implant. The driver engaging element 70 comprises a raised rectangular portion 62 and a central threaded opening 65, for engaging the driver apparatus, shown in Figure 4c and Figure 4d. The driving equipment 100 comprises a central tubular roc 102 having a thread fitting into opening 65 in the implant. An enlarged knurled knob 106 is affixed to the other end of the rod 102 for ease in turning. The central rod 102 is enclosed within a hollow tubular member 108, having a narrow lower portion 110 and an increased diameter upper portion 112. At the end of the lower portion 110 is a attachment member 114, having a generally rectangular depression 116 for complementing the driver engaging element 70 of the implant 50. A pair of handles 118 and 120 extend perpendicular from the upper position 112 of the tubular member 108 to assist in turning the driver 100.

[0055] The operation is performed in the following manner: (Example Lumbar Spine Posterior Approach) A skin incision is made directly over the interspace to be operated on. The dissection is carried down along side of the superspinous and intraspinous ligaments preserving those structures. A semi hemi laminotomy is

performed at the upper level, removing sufficient bone to allow access into the interspace. The ligament flavum is removed and then the dural sac is protected by retracting it medially along with the traversing (inferior) nerve root. The superior nerve root or the root exiting beneath the pedicle at level above is visualized and protected.

[0056] At this time the drill sleeve 10 is placed into the spinal canal with both nerve roots directly inspected and protected. The drill sleeve 10 is imbedded by teeth 12 spanning the disc space from the midline over and it is seated into the two vertebrae V across the disc D space by using a driver 20. Once this is done, the driver 20 is removed and a retaining sleeve 15 is placed through the drill sleeve 10. Once sealed, sleeve 10 provides absolute protection to the dural sac and nerve roots as the remaining surgery is performed entirely through this sleeve.

[0057] The inner sleeve allows for the difference between the outside diameter of the drill 22 and the outside diameter of the threads 53 of the cylindrical implant 50. This then makes it possible to perform the entire operation through the lumen of the imbedded outer sleeve despite the differences in diameter between the drill and the implant.

[0058] A drill 22 is then placed in the retaining sleeve 15. The drill 22 is of such a length that it can not penetrate more then 28 millimeters beyond the end of the drill sleeve 10. This, of course, could be varied and made smaller for enhanced safety. However at the present time 27 to 28 millimeters seems to be safe for probably 3 standard deviations of the population. The drill 22 is attached to a power unit and the drilling takes place.

[0059] The recessed central area between the reduced portion 26 allows for the accumulation of the debris generated by the drilling. At this time, leaving the outer sleeve firmly embedded, the retaining sleeve 15 is removed with the drill 22 as a single unit. All the vertebrae and disc debris that was generated during the drilling is contained within the recess and against the inside wall of the retaining sleeve 15 and can not come out within the spinal canal. Once the retaining sleeve 15 and drill 22 is out of the patient's operative field, all of the material so generated can be removed.

[0060] The next step is that a screw tap is put down through the drill sleeve 10. The tap also has a collar on it that will automatically stop the tap from extending beyond 28 millimeters of penetration. The tap itself has a blunt nose that would also avoid any perforation. The tap is then removed. The tap size has deliberately been selected so that it's inner root diameter is 1.3 millimeters greater than the outside diameter of the drill 22. This insures that the interspace will be distracted by at least that much once the implant is placed. The tap has its outside diameter 1.2 millimeters greater than its root diameter. The tap is removed and the space is now prepared to accept the cylindrical implant 50.

[0061] The Implant 50 is prepared by utilizing the trephine, a hollow drill, to obtain a core of pure cancellous bone from the patients iliac crest of slightly smaller diameter than the internal diameter of the implant but approximately 6mm longer. The implant 50 is placed in a press like device like an ammo loader and the bone graft measuring approximately 32 millimeters is then compressed into the hollow body of the implant (26mm) so that the bone graft fills the opening 54 and extends through the openings 56. The cap 60 is then screwed on to the implant 50 by use of an allen driver/wrench and the device is ready for implantation.

[0062] The inserter/remover is such that it locks onto the implant, so that the implant can be moved either clockwise or counter-clockwise, screwed or unscrewed. The implant itself has for its root diameter the same exact root diameter as the tap which as already noted is already 1.3 millimeters greater than the drill and has an cutside diameter, 1.5 millimeters greater than its root. This is also .3 millimeters greater than the threads cut by the tap so that in inserting the device it is actually cutting through previously uncut bone helping to insure that it locks in firmly. The threads on the implant 50 are locking threads so that it is easier to screw the device in than for it to be unscrewed. However, with sufficient torque it is possible to extract the device if ones so desires.

[0063] Once the implant has been seated it is able to be inserted only 28 millimeters. Since the implant 50 is only 26 millimeters in length, this virtually guarantees that the implant 50 will be recessed into the vertebral bodies more than 2 millimeters and can not protrude into the spinal canal.

[0064] Similarly, the implants shown in Figure 4b can be implanted. The implant in Figure 4b is a modified solid, having extensive channelling throughout, and has no cap. A central opening 61 permits insertion of the bone graft material into the interior of the implant.

[0065] These implants have a surface configuration such as to induce bone ingrowth through the implant, and into the wall of the vertebrae in effect inducing fusion from one vertebrae in joint to the other, thereby eventually making the implant itself superfluous as the bone would do the work.

[0066] The implant itself, because of its being made of stronger material than bone, would provide structural support to the two vertebrae while awaiting bone ingrowth. Once the bone ingrowth occurred, however, the implant would be firmly and permanently fixed in place.

[0067] As shown in Figure 4, more than one implant is inserted into the disc space, thereby preventing the rocking motion that would result in the difficulties referred to above in the discussion of the Bagby invention.

Claims

1. Apparatus for use in human spinal surgery for the fusion of adjacent vertebral bodies (V) through a

disc space, said apparatus being used for preparing across a spinal disc (D) an implantation space and for providing protection to neurological and vascular structures proximate the disc space while inserting a spinal implant (50) into the implantation space as formed by a drill across the disc space and into a portion of the adjacent vertebral bodies at the circumference of the implatation space, said apparatus comprising:

the spinal implant (50) comprising at least one thread on its exterior and having an outside diameter adapted to penetrably engage the adjacent vertebral bodies (V) and having a root diameter that is smaller than said penetrating outside diameter,
a hollow tubular rigid guard (10) for providing protected access to prepare across the spinal disc (D) the implantation space and to insert into the implantation space the spinal implant (50), said guard (10) having an inside diameter being greater than said outside diameter of the implant and having a permanently fixed diameter tubular end comprising a plurality of axially projecting means, said plurality of projecting means circumferentially arranged at said tubular end such as to extend between and engage into said adjacent vertebral bodies (V), and
the drill (22) for forming through said guard (10) the implantation space, said drill (22) having a shaft with a cutting portion (28) and a driving end (24) opposite said cutting portion (28), said cutting portion (28) having an outside diameter that is sufficiently smaller than said outside diameter of the implant (50) and the inside diameter of said guard (10) to permit said outside diameter of the implant (50) to penetrably engage into said portion of the adjacent vertebral bodies (V) at the circumference of the implantation space.

2. The apparatus of claim 1, wherein said plurality of means comprises a plurality of teeth (12).

3. The apparatus of claim 2, wherein said teeth are at least in part co-linear with the outer perimeter of said end of the guard (10).

4. The apparatus of any of claims 1-3, wherein the outside diameter of the cutting portion of the drill (22) is smaller than said root diameter of the implant (50),

5. The apparatus of any of claims 1-4, further comprising a tap for tapping the implantation space through said guard (10), said tap having an outside diameter that is greater than said diameter of said cutting portion of said drill and slightly smaller than the inside diameter of said guard.

6. The apparatus of claim 5, wherein the root diameter of the tap is the same as the root diameter of the implant.

7. The apparatus of any of claims 1-6, further comprising a removable inner sleeve (15) disposed within said guard (10) for positioning and aligning said drill (22), said inner sleeve (15) having an outside diameter slightly smaller than the inside diameter of the guard and an inside diameter slightly greater than the outside diameter of the cutting portion (28) of the drill (22) to allow for the difference in size between the outside diameter of the drill (22) and said outside diameter of the implant (50) and inside diameter of the guard (10).

8. The apparatus any of claims 1-7, wherein said drill (22) further comprises a narrowed portion (26) for collecting debris generated by the operation of said drill (22) intermediate said cutting portion (28) and driving end (24).

9. The apparatus any of claims 1-8, further comprising an insertion device (100) for inserting the implant (50) into the implantation space through said guard (10), said insertion device (100) comprising:

an elongated member (102) having means (104, 114) for lockably engaging an engagement element (70) portion (60) of the implant (50), whereby when said lockably engaging means (104, 114) locks onto the implant (50), said insertion device (100) may be rotated in either direction, pushed, and pulled for insertion of the implant (50) into the spine without disengaging the implant (50) except by the deliberate disengaging the implant (50) by the operator.

10. The apparatus of claim 9, wherein the implant (50) has a first co-operating member (63) and said lockably engaging means (104, 114) comprises a corresponding second co-operating member (116) for co-operatively engaging said first co-operating member (63).

11. The apparatus of any of claims 1-10, wherein said guard has a length defined by said end configured to be placed against the adjacent vertebral bodies (V) and an opposite proximal end forming said length, said guard having a substantially uniform cross section along said end to be placed against the adjacent vertebral bodies.

12. The apparatus of any of claims 1-11, wherein said guard is configured for insertion into the lumbar

spine from the posterior approach.

Patentansprüche

1. Vorrichtung zum Gebrauch in der Wirbelsäulenchirurgie bei Menschen zur Fusion von benachbarten Wirbelkörpern (V) über einen Bandscheibenzwischenraum, wobei die Vorrichtung dazu benützt wird, um quer durch eine Bandscheibe (D) hindurch einen Implantatraum zu schaffen und um Schutz für Nerven- und Gefäßstrukturen im Umfeld des Bandscheibenraums zu bieten, während ein Wirbelsäulenimplantat (50) in den Implantatraum eingefügt wird, der durch einen Bohrer quer durch den Bandscheibenzwischenraum hindurch und in einen Abschnitt der benachbarten Wirbelkörper am Umfang des Implantatraumes geformt wird, wobei die Vorrichtung aufweist:

   das Wirbelsäulenimplantat (50), das mindestens eine Gewindewindung an der Außenseite aufweist und einen Außendurchmesser hat, der dergestalt ist, daß er in die benachbarten Wirbelkörper (V) durchdringend eingreift, und einen Kerndurchmesser hat, der kleiner als der durchdringende Außendurchmesser ist,
   eine hohle, rohrförmige, steife Schutzvorrichtung (10), um geschützten Zugang zu bieten, um den Implantatraum durch die Bandscheibe (D) zu schaffen und das Wirbelsäulenimplantat (50) in den Implantatraum einzuführen, wobei die Schutzvorrichtung (10) einen Innendurchmesser aufweist, der größer ist als der Außendurchmesser des Implantats, sowie ein rohrförmiges Ende mit permanent gleichbleibendem Durchmesser mit einer Vielzahl von axial vorstehenden Mitteln, wobei die Vielzahl von vorstehenden Mitteln am Umfang an dem rohrförmigen Ende so umfangsweise angeordnet ist, daß sie sich zwischen den benachbarten Wirbelkörpern (V) erstrecken und in diese eingreifen, und
   den Bohrer (22), der dazu bestimmt ist, durch die Schutzvorrichtung (10) hindurch den Implantatraum zu bilden, wobei der Bohrer (22) einen Schaft mit einem Schneideabschnitt (28) und mit einem dem Schneideabschnitt (28) gegenüber liegenden Antriebsende (24) aufweist, und wobei der Schneideabschnitt (28) einen Außendurchmesser hat, der genügend kleiner als der Außendurchmesser des Implantats (50) und als der Innendurchmesser der Schutzvorrichtung (10) ist, so daß der Außendurchmesser des Implantats (50) in den Abschnitt der benachbarten Wirbelkörper (V) am Umfang des Implantatraums durchdringend eingreifen kann.

2. Vorrichtung gemäß Anspruch 1, wobei die Vielzahl von Mitteln eine Vielzahl von Zähnen (12) aufweist.

3. Vorrichtung gemäß Anspruch 2, wobei die Zähne mindestens teilweise kolinear mit dem Außenumfang des Endes der Schutzvorrichtung (10) sind.

4. Vorrichtung gemäß einem der Ansprüche 1-3, wobei der Außendurchmesser des Schneideabschnitts des Bohrers (22) kleiner als der Kerndurchmesser des Implantats (50) ist.

5. Vorrichtung gemäß einem der Ansprüche 1-4, welche weiterhin einen Gewindeschneider aufweist zum Gewindeschneiden im Implantatraum durch die Schutzvorrichtung (10) hindurch, wobei der Gewindeschneider einen Außendurchmesser aufweist, der größer als der Durchmesser des Schneideabschnitts des Bohrers ist und geringfügig kleiner als der Innendurchmesser der Schutzvorrichtung.

6. Vorrichtung gemäß Anspruch 5, wobei der Kerndurchmesser des Gewindeschneiders gleich dem des Implantats ist.

7. Vorrichtung gemäß einem der Ansprüche 1-6, welche weiterhin eine entfernbare innere Hülse (15) aufweist, die in der Schutzvorrichtung (10) angeordnet ist, um den Bohrer (22) zu positionieren und in eine Linie zu bringen, wobei die innere Hülse (15) einen Außendurchmesser aufweist, der geringfügig kleiner ist als der Innendurchmesser der Schutzvorrichtung, und einen Innendurchmesser aufweist, der geringfügig größer ist als der Außendurchmesser des Schneideabschnitts (28) des Bohrers (22), um den Größenunterschied zwischen dem Außendurchmesser des Bohrers (22), dem Außendurchmesser des Implantats (50) und dem Innendurchmesser der Schutzvorrichtung (10) zuzulassen.

8. Vorrichtung gemäß einem der Ansprüche 1-7, wobei der Bohrer (22) weiterhin einen verengten Abschnitt (26) zur Sammlung von Staub, der durch die Betätigung des Bohrers (22) erzeugt wird, zwischen dem Schneideabschnitt (28) und dem Antriebsende (24) aufweist.

9. Vorrichtung gemäß einem der Ansprüche 1-8, welche weiterhin eine Einsetzvorrichtung (100) aufweist, um das Implantat (50) in den Implantatraum durch die Schutzvorrichtung (10) hindurch einzusetzen, wobei die Einsetzvorrichtung (100) aufweist:

   ein längliches Bauteil (102) mit Mitteln (104, 114), um an einem mit einem Angriffselement (70) versehenen Abschnitt (60) des Implantats

(50) verriegelnd anzugreifen, wobei, wenn das verriegelbar angreifende Mittel (104, 114) an dem Implantat (50) verriegelt ist, die Einsetzvorrichtung (100) zum Einsetzen des Implantats (50) in die Wirbelsäule in beide Richtungen gedreht werden kann, geschoben werden kann sowie gezogen werden kann, ohne das Implantat (50) zu entriegeln, es sei denn, das Implantat (50) wird durch den Ausführenden absichtlich entriegelt.

10. Vorrichtung gemäß Anspruch 9, wobei das Implantat (50) ein erstes kooperierendes Bauteil (63) aufweist, wobei das verriegelbar angreifende Mittel (104, 114) ein zugehöriges zweites kooperierendes Bauteil (116) aufweist, um kooperierend am ersten kooperierenden Bauteil (63) anzugreifen.

11. Vorrichtung gemäß einem der Ansprüche 1-10, wobei die Schutzvorrichtung eine Länge aufweist, die durch jenes Ende, welches so gestaltet ist, daß es gegen die benachbarten Wirbelkörper (V) plaziert werden kann, und durch ein gegenüberliegendes proximales Ende definiert ist, welches diese Länge bildet, wobei die Schutzvorrichtung einen im wesentlichen einheitlichen Querschnitt entlang dem Ende, das gegen die benachbarten Wirbelkörper plaziert werden soll, aufweist.

12. Vorrichtung gemäß einem der Ansprüche 1-11, wobei die Schutzvorrichtung so gestaltet ist, daß sie in die Lendenwirbelsäule von hinten her eingeführt wird.

Revendications

1. Dispositif destiné à être utilisé dans la chirurgie rachidienne humaine pour la fusion de corps vertébraux (V) adjacents à travers un espace de disque intervertébral, ledit dispositif étant utilisé pour préparer à travers un disque intervertébral (D) un espace d'implantation et pour assurer la protection des structures neurologiques et vasculaires proches de l'espace intervertébral pendant qu'on insère un implant rachidien (50) dans l'espace d'implantation qui a été formé par un foret à travers l'espace intervertébral et dans une partie des corps vertébraux adjacents, au droit de la circonférence de l'espace d'implantation, ledit dispositif comprenant :

l'implant rachidien (50) comprenant au moins un filetage sur sa surface extérieure et ayant un diamètre extérieur adapté pour attaquer avec pénétration les corps vertébraux (V) adjacents, et cet implant ayant un diamètre à fond de filet qui est plus petit que le diamètre extérieur pénétrant,

une protection rigide tubulaire creuse (10) destinée à assurer un accès protégé pour préparer l'espace d'implantation à travers le disque intervertébral (D) et pour insérer l'implant rachidien (50) dans l'espace d'implantation, ladite protection (10) ayant un diamètre intérieur plus grand que ledit diamètre extérieur de l'implant et ayant une extrémité tubulaire de diamètre fixe en permanence qui comprend une pluralité de moyens en saillie axiale, ladite pluralité de moyens en saillie étant agencés circonférentiellement à ladite extrémité tubulaire de manière à s'étendre entre lesdits corps vertébraux (V) adjacents et à les attaquer, et

le foret (22) destiné à former l'espace d'implantation à travers ladite protection (10), ledit foret (22) ayant une tige munie d'une portion de coupe (28) et une extrémité d'entraînement (24) à l'opposé de ladite portion de coupe (28), ladite portion de coupe (28) ayant un diamètre extérieur qui est suffisamment plus petit que ledit diamètre extérieur de l'implant (50) et que le diamètre intérieur de ladite protection (10) pour permettre audit diamètre extérieur de l'implant (50) de coopérer avec pénétration avec ladite portion des corps vertébraux (V) adjacents au droit de la circonférence de l'espace d'implantation.

2. Dispositif selon la revendication 1, dans lequel ladite pluralité de moyens comprennent une pluralité de dents (12).

3. Dispositif selon la revendication 2, dans lequel lesdites dents sont au moins en partie colinéaires avec le périmètre extérieur de ladite extrémité de la protection (10).

4. Dispositif selon une quelconque des revendications 1- 3, dans lequel le diamètre extérieur de la portion de coupe du foret (22) est plus petit que ledit diamètre à fond de filet de l'implant (50)

5. Dispositif selon une quelconque des revendications 1- 4, comprenant en outre un taraud destiné à tarauder l'espace d'implantation à travers ladite protection (10), ledit taraud ayant un diamètre extérieur qui est plus grand que ledit diamètre de la portion de coupe dudit foret et légèrement plus petit que le diamètre intérieur de ladite protection.

6. Dispositif selon la revendication 5, dans lequel le diamètre à fond de filet du taraud est le même que le diamètre à fond de filet de l'implant.

7. Dispositif selon une quelconque des revendications 1 à 6, comprenant en outre une fourrure intérieure amovible (15) disposée dans ladite protection (10)

pour positionner et aligner ledit foret (22), ladite fourrure intérieure (15) ayant un diamètre extérieur légèrement plus petit que le diamètre intérieur de la protection et un diamètre intérieur légèrement plus grand que le diamètre extérieur de la portion de coupe (28) du foret (22) pour admettre la différence de dimension entre le diamètre extérieur du foret (22), ledit diamètre extérieur de l'implant (50) et le diamètre intérieur de la garde (10).

8. Dispositif selon une quelconque des revendications 1-7, dans lequel ledit foret (22) comprend en outre une portion amincie (26) pour collecter les débris formés par le travail dudit foret (22) entre ladite portion de coupe (28) et l'extrémité d'entraînement (24).

9. Dispositif selon une quelconque des revendications 1-8, comprenant en outre un dispositif d'insertion (100) destiné à insérer l'implant (50) dans l'espace d'implantation à travers ladite protection (10), ledit dispositif d'insertion (100) comprenant :

un élément allongé (102) présentant des moyens (104, 114) pour attaquer avec verrouillage une portion (60) d'élément d'attaque de l'implant (50), de sorte que, lorsque lesdits moyens d'attaque à verrouillage (104, 114) se verrouillent sur l'implant (50), on peut faire tourner ledit dispositif d'insertion (100) dans l'un ou l'autre sens, le pousser et le tirer pour l'insertion de l'implant (50) dans la colonne vertébrale sans dégager l'implant (50), sauf par dégagement délibéré de l'implant (50) par l'opérateur.

10. Dispositif selon la revendication 9, dans lequel l'implant (50) possède un premier élément de coopération (63), et ledit moyen d'attaque à verrouillage (104, 114) comprend un deuxième élément de coopération (116) correspondant destiné à entrer en prise par coopération avec ledit premier élément de coopération (63).

11. Dispositif selon une quelconque des revendications 1-10, dans lequel ladite protection a une longueur définie par ladite extrémité configurée pour être placée contre les corps vertébraux (V) adjacents et par une extrémité proximale opposée et qui forme ladite longueur, ladite protection ayant une section sensiblement uniforme le long de ladite extrémité qui doit être placée contre les corps vertébraux adjacents.

12. Dispositif selon une quelconque des revendications 1-11, dans lequel ladite protection est configurée pour être insérée dans la colonne vertébrale lombaire en approche postérieure.

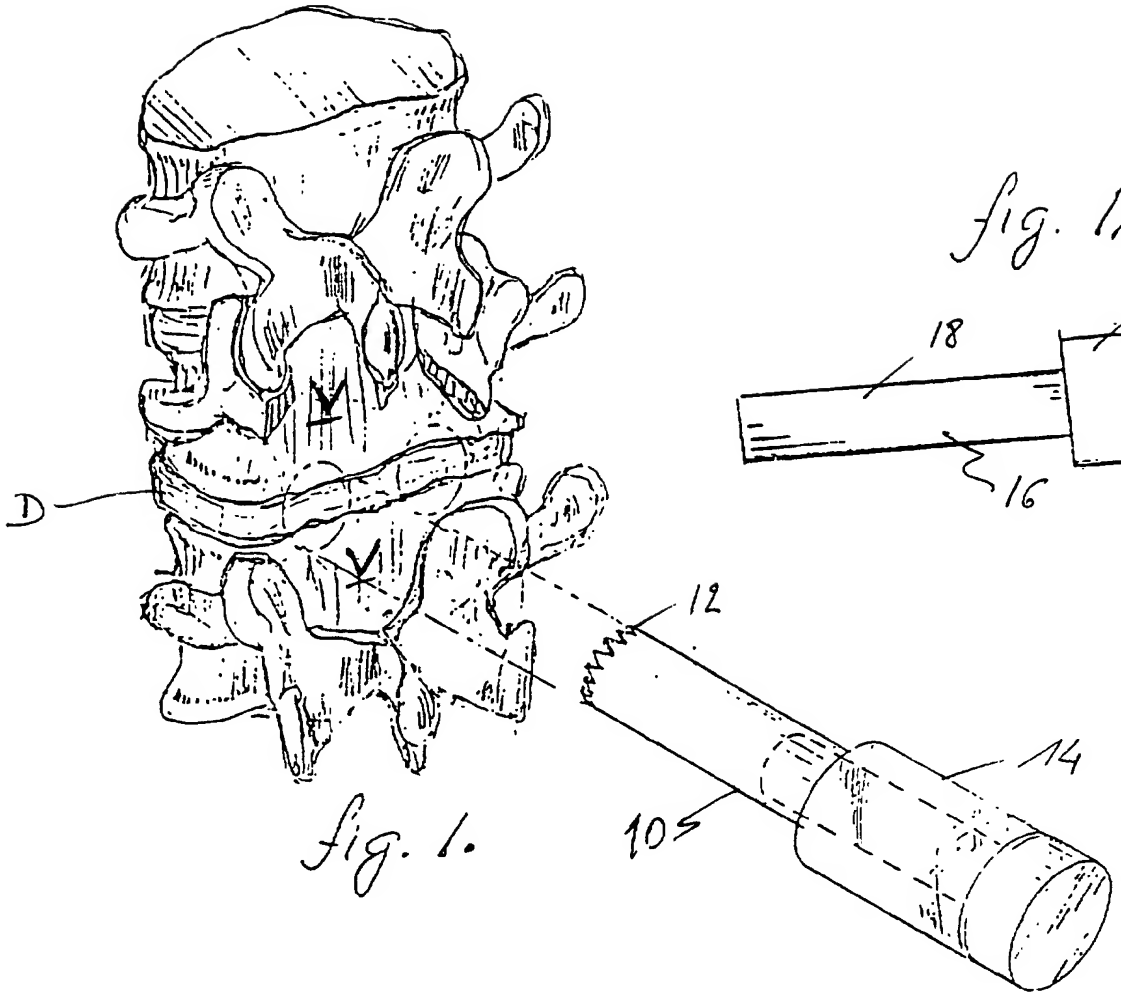


fig. 1.

fig. 1A.

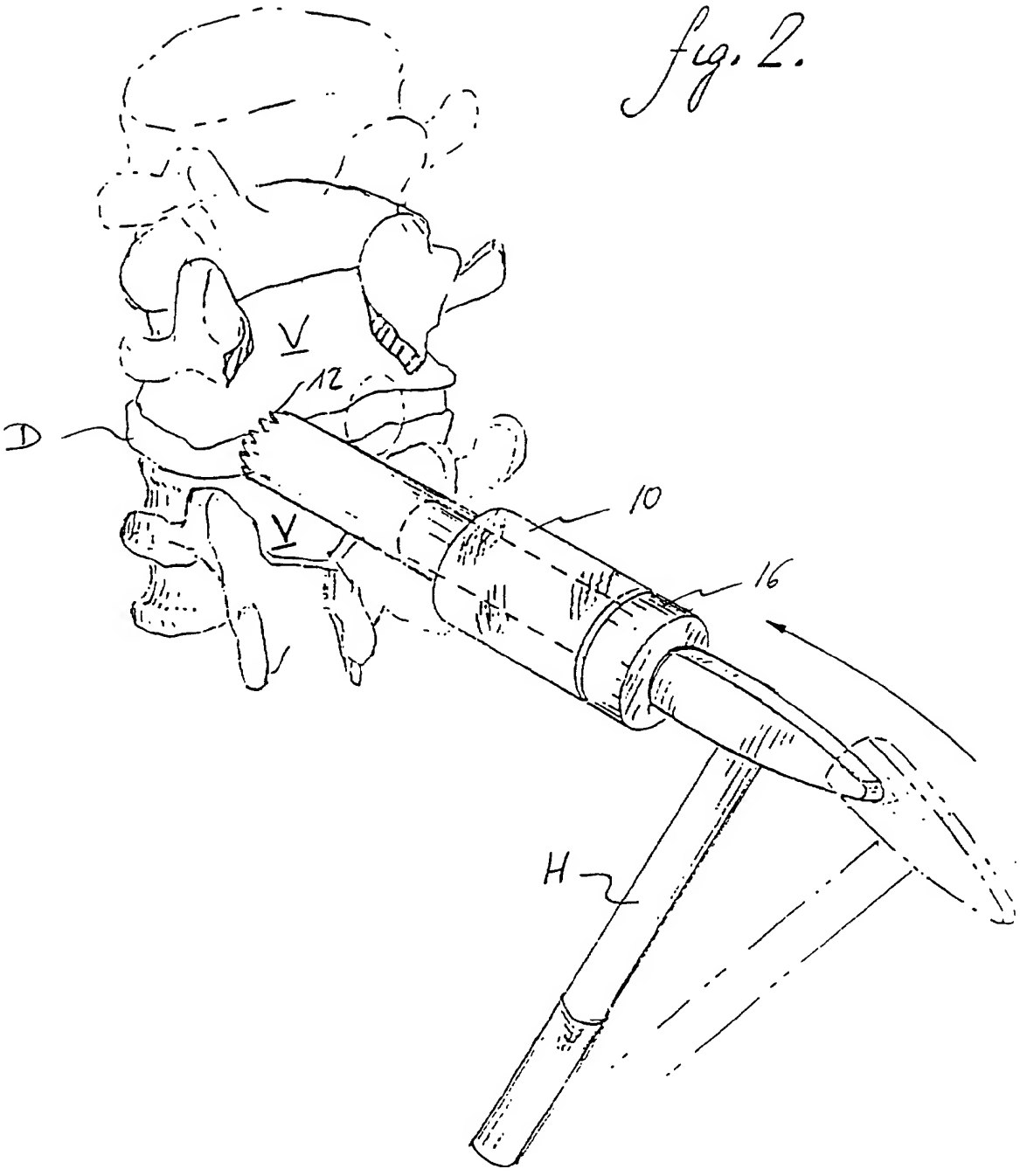
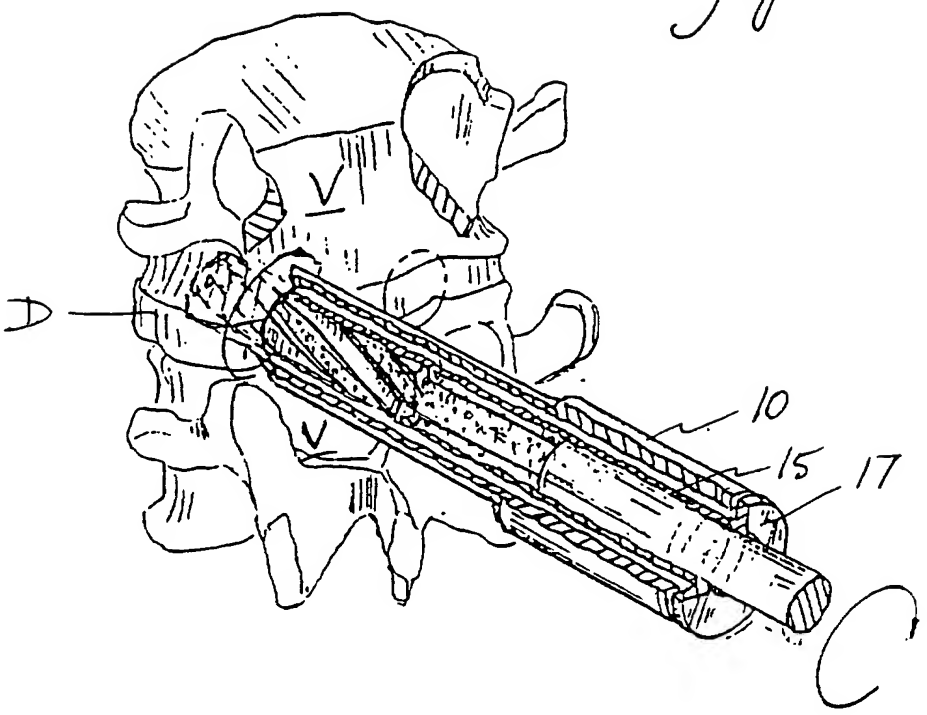


fig. 2.

fig. 3.



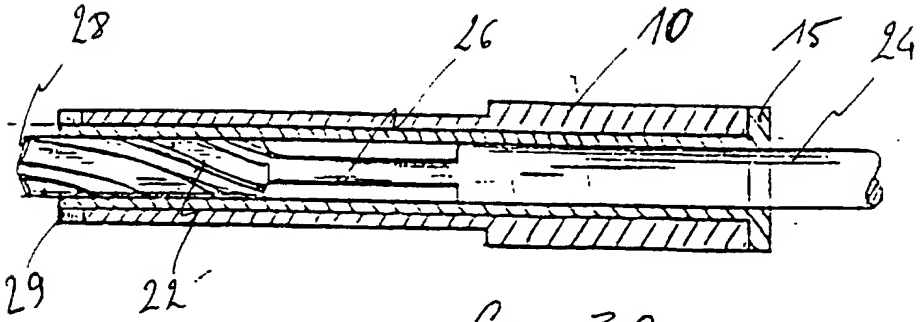


fig. 3A.

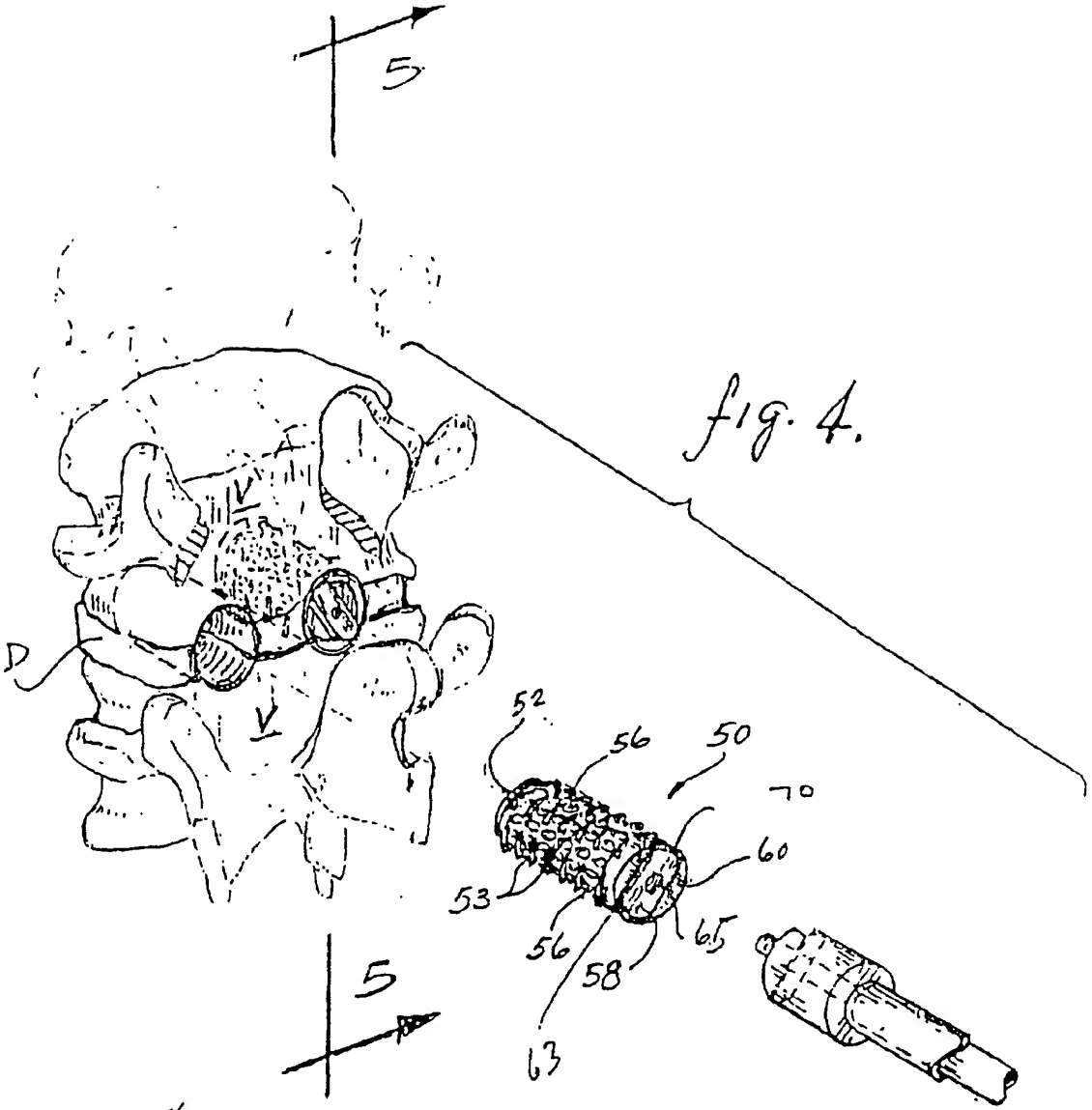


fig. 4.

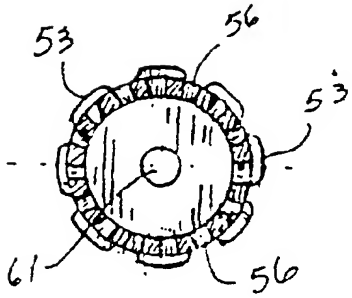


fig. 4b.

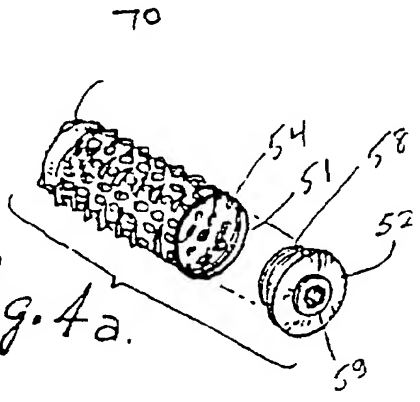


fig. 4a.

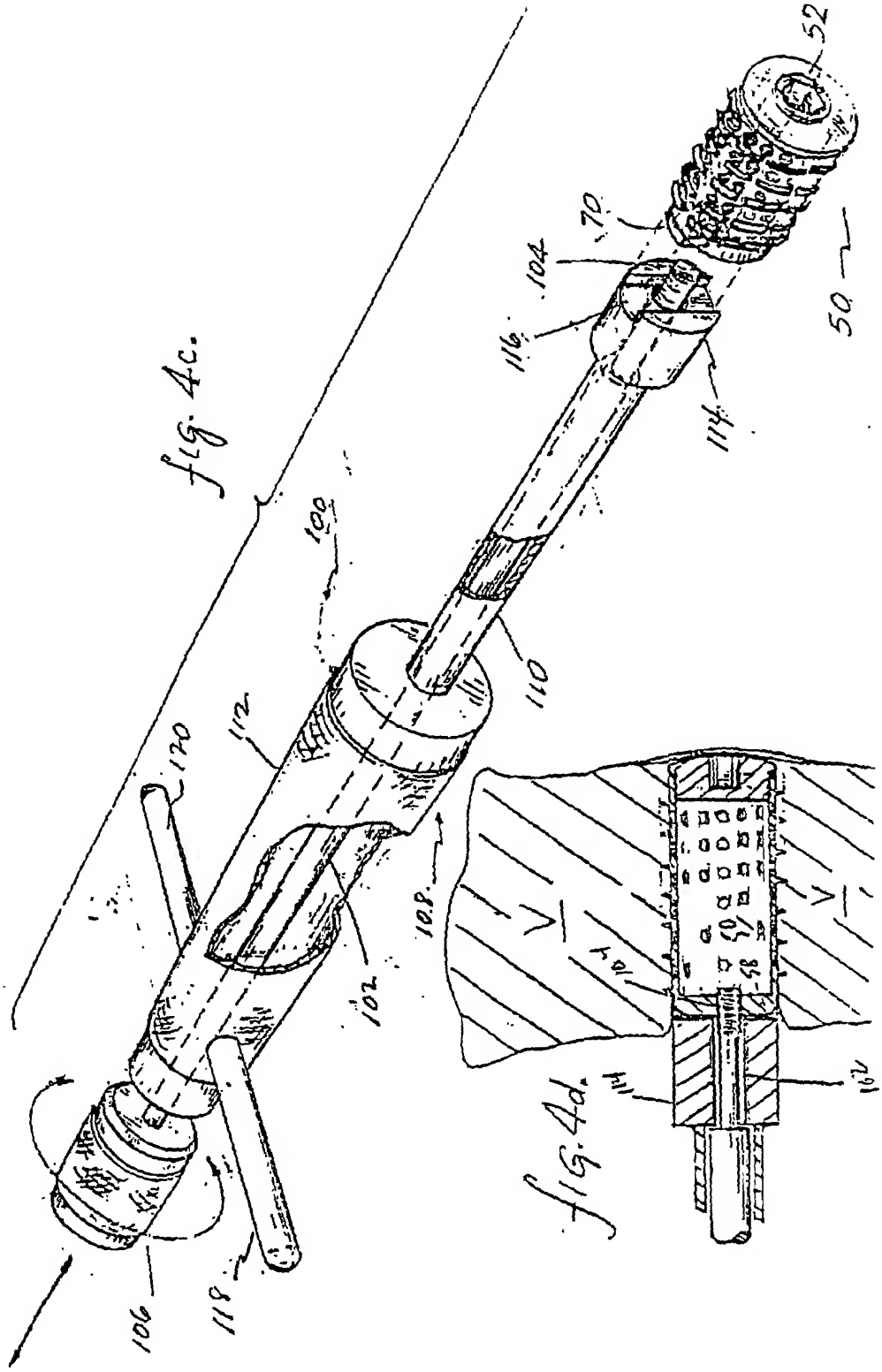


Fig. 4c.

Fig. 4d.

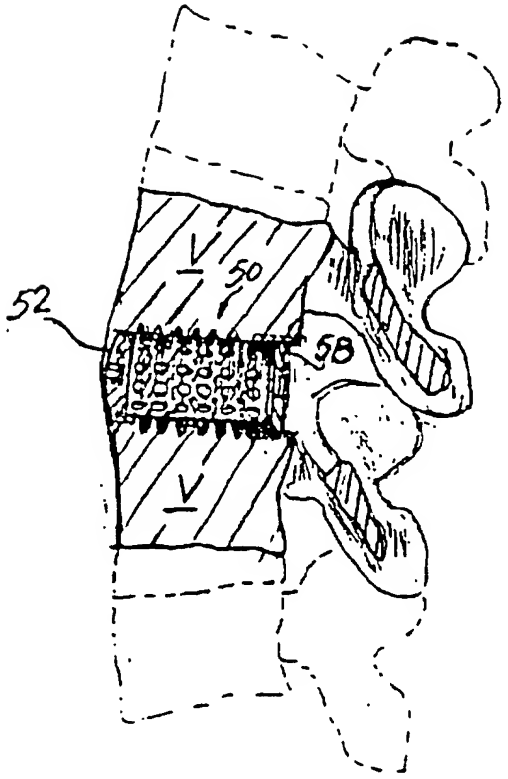


fig. 5.